

REMARKS

This is a response to office action dated September 30, 2004. Claims 1-7, 9-26, and 33-70 are currently pending – claims 33-70 being newly added. Claims 8 and 27-32 have been canceled. No new matter has been added and all the amendments and new claims find ample support in the specification.

The numbered paragraphs below correspond to the Examiner's numbered paragraphs:

1. Claims 8 and 27-32 have been canceled.

2. Claims 12 and 14 have been withdrawn from consideration. Claims 12 and 14 have also been amended. Applicants respectfully request reconsideration of claims 12 and 14 since they are dependent from claim 1 and claim 1 is believed to be in condition for allowance.

3./4. Claims 1-7, 11, 13, 17-19 and 21-24 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Castro et al. (U.S. Patent No. 6,395,326) ("Castro").

With respect to claims 1-7, 11, 13, 17-19, 21 and 22, Applicants respectfully disagree. As correctly indicated by the Examiner, Castro does teach a heating element for curing or drying of the coating substance. As indicated in col. 11, lines 11-16, "a heating assembly is used for controlling drying and/or curing of a coating on prosthesis 12. As shown in FIG. 5A, heating assembly 52 can be a device including a heating conduit 45, a heating nozzle 56 having an orifice 58 through which heat is delivered and a heating control system 60." **Castro fails to teach that the heating assembly does or is capable of directing a gas as claimed.** There is **absolutely no teaching in Castro that a heated or cooled gas is applied to the stent via the nozzle.** Application of heat in Castro can be by many means, such as a heated coil or a

conductive pin positioned in the opening of the nozzle (charged pin that can glow and generate heat). Using gas cannot be read into the teaching of Castro since Castro has no indication of its use. Moreover, there is absolutely no teaching in Castro that “if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to inhibit the evaporation of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to induce the evaporation of the solvent,” as recited by Claim 1. **Castro teaches absolutely no condition of temperature adjustment based on the vapor pressure 17.54 Torr of the solvent.** Applicants agree that dimethylacetamide is disclosed in Castro, including a variety of other solvents that are also disclosed by the current invention. However, **the mere disclosure of a solvent having a low vapor pressure does not amount to the teaching of a method of adjusting gas temperature based on the volatility of the solvent used.** Applicants respectfully submit that the Examiner has fallen significantly short of showing how Castro anticipated each and every element of the claims and Applicants respectfully submit that Claim 1 is patentably allowable over Castro. Claims 2-7, 11, 13, 17-19, 21 and 22 depend from claim 1 and are patentably allowable for at least the same reason.

With respect to claims 23 and 24, Applicants also respectfully disagree. Again, although Castro does teach heating, there is absolutely no teaching in Castro of “blowing a gas, from a gas blower, directly onto the implantable medical device,” as recited by claim 23. The use of heated or cooled gas blown onto an implantable medical device is not disclosed by Castro. Moreover, Castro fails to teach a method wherein the temperature of the gas is dependent on the volatility of the solvent as recited by claim 23. Accordingly, Applicants believe claim 23 is also allowable over Castro. Claim 24 depends from claim 23 and is allowable for at least the same reason.

Withdrawal of the rejection is kindly requested.

5./6./7. Claims 9, 10, 15, 16, 20, 25, and 26 have been rejected under 35 U.S.C. 103(a) as being obvious over Castro. As indicated above, claims 1 and 23 are patentable over Castro. Claims 9, 10, 15, 16, 20, 25 and 26 depend from claims 1 and 23 and are therefore patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

8. Claims 1-7, 9-11, 13 and 15-26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ding et al. (U.S. Patent No. 6,358,556) (“Ding”) in view of You et al. (U.S. Patent No. 6,407,009) (“You”). Applicants respectfully disagree based on the following reasons:

(A) First, with respect to claim 1, the references alone or in combination fail to teach each and every element of the claim. Neither Ding nor You teach that the temperature of the gas is based on a solvent vapor pressure of 17.54 Torr at ambient temperature, as recited in claim 1. For this reason alone, claim 1 is patentably allowable over Ding in view of You. Claims 2-7, 9-11, 13 and 15-22 depend from claim 1 and are allowable for at least the same reason.

(B) With respect to Claim 23, the references alone or in combination fail to teach “blowing a gas, from a gas blower, directly onto the implantable medical device.” Ding simply fails to teach the use of any kind of gas blower for blowing gas (Applicants note that the claim has been amended for clarity so as to distinguish between a coating dispenser and a gas blower). In turn, the Applicants assume that the Examiner is relying on You to fulfill this deficiency. However, Applicants submit that You falls short of this teaching. You teaches that “the chamber space 103 can be cooled adiabatically by using the bias gas stored under pressure and released into the chamber at a pressure lower than the storage pressure of the gas” (col. 5 lines 66 and 67 continuing to col. 6, lines 1 and 2). Releasing gas into a chamber to cool the chamber holding a semiconductor substrate is not equivalent to “blowing a gas ... directly onto the implantable medical device.” In one instance, cold gas is introduced in an environment in which a substrate

is placed and in the other instance a gas is blown directly onto the substrate. To make an analogy, if on a warm day the Examiner is sitting in an air conditioned room, the air conditioning may be blowing in the room but not directly onto the Examiner. The Examiner will feel the coolness of the room but not the blowing of the air conditioning. The Examiner has to stand right in front of the air conditioning and at a distance close enough that the air is directly being applied to the Examiner or in other words, the Examiner is feeling the cool air on her face. One is not the same as the other. For at least this reason claim 23 is patentably allowable over the combination of the references. Claims 24-26 depend from claim 23 and are allowable for at least the same reason.

(C) The case law is very clear on the issue of obviousness, in that “in order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention was concerned.” In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Applicants agree that Ding is in the field of Applicant’s invention. You, however, relates to deposition of semiconductor thin films. Applicants believe that it is safe to say that You is not within the field of Applicant’s endeavor of medical devices, unless the Examiner has broadened the endeavor to include any type of coating processing. If this is the case, Applicants respectfully request that the examiner go on the record to indicate that she believes that You is in the field of the Applicants’ endeavor. If this is in fact the Examiner’s position, then the court’s holding of “being in the field of applicant’s endeavor” is **left without a meaning** because under the Examiner’s definition, what ever technology that has to do with the deposition of a coating must be in the same endeavor as the current invention, regardless of what it is. Stated by way of example, painting a house, under the Examiner’s reasoning, would be in the field of the applicants’ endeavor since it has to do with deposition of a polymer material. To continue with this line of reasoning, “one of ordinary skill in the art” can even be a contractor that paints a

house. Applicants with all due respect submit that this line of reasoning would be in error and very unreasonable.

Now, with respect to the second branch of the test, namely, if it is not in the same field of endeavor, then the reference must be reasonably pertinent to the particular problem with which the invention was concerned. The Examiner is on record in stating that the teaching of the references is reasonably pertinent to the particular problem of preventing the coating from “cracking” (pages 6 and 7 of the office action). This is incorrect. **The sheer fact that the Examiner is incorrect, on the record, about the combination of references being pertinent to the problem of preventing cracking should be sufficient to hold that the obviousness rejection is without merit.**

Problems with stent coating cracking have to do with the brittleness and glass transition temperature of the polymer and the stress applied to the coating by the stent during crimping and/or expansion of the stent. As described by the specification of the present invention, the problems which the invention at bar is addressing includes “cob-web” formation between stent struts, “pool” formation on the struts, drug retention, minimization of interaction of the drug to the solvent (which could adversely affect of the drug) and enabling the stent to hold enough drug for the effective treatment of the patient. As indicated by the specification, initial portions of the liquid composition containing a drug are deposited on the stent. However, it is believed that as liquid composition continues to be applied to the stent, layer of composition form on top of one another. It is further believed that the drug, when exposed to solvents in the upper layer, can re-dissolve into the upper layer or be extracted out from the coating. Having the drug maintained in merely the upper region of the coating provides for a short residence time of the drug at the treatment site or burst release of the drug out from the coating. **There is nothing in the reference that is even remotely pertinent to the particular problem with which this invention is concerned.**

(D) In Stratoflex, Inc. v Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983), the court stated that the problem confronting inventor was preventing electrostatic buildup in PTFE tubing caused by hydrocarbon fuel flow while precluding leakage of fuel. Two prior art references relied upon were in the rubber hose art, both referencing the problem of electrostatic buildup caused by fuel flow. The court found that because PTFE and rubber are used by the same hose manufacturers and experience the same and similar problems, a solution found for a problem experienced with either PTFE or rubber hosing would be looked to when facing a problem with the other.

The facts at bar are severely in contrast to what has been presented by Stratoflex. **The Ding reference has no mention of stent coating problems. The You reference is directed at preventing cracking of residual deposited material as well as increasing the dielectric and mechanical strength of the material leading to longer lifetimes for semiconductor devices.** Neither of the references discusses problems addressed by the present invention. Drug eluting stents which include intricate geometries which have been incredibly challenging to coat, need sever FDA scrutiny, and have been in development for over 6 years with only two companies having a product in the market (Boston Scientific and Johnson and Johnson), do not share the same manufacturing issues as a large and flat surface of a semiconductor wafer. Moreover, with all due respect to the Examiner, **one dealing with the issue of preventing the drug from migrating to upper layers of a stent coating does not look at a reference for increasing the dielectric strength of a semiconductor device to make adjustment to the manufacturing process.**

(E) Finally, Applicants also submit that the Examiner has not established a *prima facie* case of obviousness. There is absolutely no motivation in the references to make the combination. Ding does not mention anything with respect to coating defects as well as drug migration to upper regions of the coating or out from the stent. Ding does not mention that

adverse affect that solvent systems could possibly have on a drug. Applicants therefore submit to the examiner, if Ding is silent on all these issues, if one reads Ding, why would one in the stent art refer to a semiconductor reference of You to correct any coating problems that Ding may have (should the Examiner maintain her rejection, applicants respectfully like an answer to this question)? Moreover, if You is directed at preventing cracking of residual deposited material as well as increasing the dielectric and mechanical strength of the material leading to longer lifetimes for semiconductor devices, why would a combination of You and Ding make sense, considering the materials used for coating stents are different than semiconductor coating materials?

Additionally, with respect to motivation, not from the reference, but in knowledge generally available to one of ordinary skill in the art, applicants submit the following: (1) this technology is a brand new technology which lacks general availability and know how; and (2) considering that even the Examiner made an error in describing the reasoning of the motivation to combine -- namely, prevention of "cracking," Applicants submit that this error in and of itself is *prima facie* evidence of non-obviousness.

The examiner has provided no objective reasoning to make the combination as required by Ex parte Levengood, 28 USPQ1300 (Bd. Pat. App. & Inter. 1993). Applicants agree that these two references can be combined -- anything can be combined; but the law is very clear, that the mere fact that the references can be combined does not render the resultant combination obvious unless there is suggestion to make the combination. The only reason why this combination was made is because the Examiner used the hindsight of the Applicants' claim to make the combination -- otherwise such a far fetch semiconductor reference would not have been used.

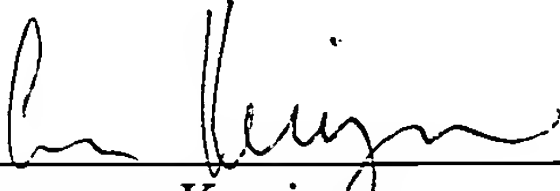
In sum, Applicants respectfully request withdrawal of all the rejections and allowance of the claims.

CONCLUSION

Applicants respectfully request issuance of the notice of allowance. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

Date: March 30, 2005
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0323
Facsimile (415) 393-9887

Respectfully submitted,


Cameron Kerrigan
Attorney for Applicants
Reg. No. 44,826